

Appl. No. 10/027,269

Amendment dated May 22, 2003

Remarks

Claims 1-54 are pending in the instant application. Claims 11-13, 17-32, 36, 43, 46, 49, 52 and 54 have been withdrawn from consideration. In the Office Action mailed November 22, 2002, the Examiner rejects claims 1-6, 8-10, 14-16, 33, 34, 38-42, 44, 45, 50, 51, and 53, and the Examiner objects to claims 7, 35, 37, 47, and 48.

By virtue of the amendments to the claims presented above, independent claims 1, 39, 44, and 51 are amended. New claims 55 and 56 are presented; new claim 55 represents a combination of original claims 1 and 7 and new claim 56 represents a combination of original claims 44 and 47. Based on the amendments and remarks made herein, Applicants respectfully request that the rejections be withdrawn and that the application be passed to allowance.

In addition, by virtue of the amendments to the claims presented above, non-elected claims 11-13, 17-32, 36, 46, 49, and 52 are allowable as they depend from allowable generic claims.

1. Remarks on Paragraph 2 of the Office Action mailed on November 22, 2002

In paragraph 1 of the Office Action mailed on November 22, 2003, the Examiner acknowledges Applicant's election of the species of claims 8-10, 14, 39-42, and 53. By virtue of the amendments to the claims presented above and described below, non-elected claims 11-13, 17-32, 36, 46, 49, and 52 are allowable as they depend from allowable generic claims.

2. Remarks on Paragraph 2 of the Office Action mailed on November 22, 2002

In paragraph 2 of the Office Action mailed on November 22, 2002, the Examiner requests clarification of the statute being relied upon for the priority claim. Priority is claimed under 35 U.S.C. § 119(e).

3. Remarks on Paragraph 4 of the Office Action mailed on November 22, 2002

In paragraph 4 of the Office Action mailed on November 22, 2002, the Examiner requests correction of the Abstract. A revised Abstract is presented above on page 2.

4. Remarks on Paragraph 5 of the Office Action mailed on November 22, 2002

In paragraph 5 of the Office Action mailed on November 22, 2002, the Examiner objects to an informality in Claim 51. Claim 51 is corrected above on page 9.

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5. Rejection of Claims 15, 16 Under 35 U.S.C. §112, Second Paragraph

In the Office Action mailed November 22, 2002, the Examiner rejects claims 15 and 16 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that the Applicants regard as the invention. Specifically, the Examiner believes that claims 15 and 16 claim an element beyond the preamble of claim 1. Claims 15 and 16 have been canceled.

6. Rejection of Claims 1-6, 8-10, 14-16, 33, 34, 39-42, 44, 45, 50, 51, 53 Under 35 U.S.C. §102(b)

In the Office Action mailed November 22, 2002, the Examiner rejects claims 1-6, 8-10, 14-16, 33, 34, 39-42, 44, 45, 50, 51, and 53 as being unpatentable under 35 U.S.C. §102(b) over U.S. Patent No. 4,286,596 issued to Rubinstein. (hereinafter "the Rubinstein patent"). With respect to claims 1-5, 8, 10, 14, 39, 41, 44, 50, 51, and 53, the Examiner believes the Rubinstein patent discloses an absorbent device that has a body, absorbent zone, application zone, and a formulation, with the application zone adjacent the proximal end. With respect to claim 6, the Examiner believes the Rubinstein patent discloses a non-absorbent material. With respect to claims 9 and 40, the Examiner believes that the Rubinstein patent discloses a reservoir in fluid communication with the surface. With respect to claims 15, 16, 42, and 45, the Examiner believes the Rubinstein patent discloses the limitations of these claims at column 4, lines 17-23. With respect to claims 33 and 34, the Examiner believes the claims are product by process limitations whose end structures are disclosed in the Rubinstein patent.

Claim 1 as amended is directed to an absorbent device adapted to deliver a therapeutic agent to a user, the device comprising a body having a proximal end and a distal end and adapted to be positioned entirely within the user, the body including an absorbency zone adjacent the distal end, wherein the absorbency zone includes absorbent material; an application zone adjacent the proximal end and spaced apart from the distal end, wherein the application zone has a surface; and a formulation including a therapeutic agent positioned substantially adjacent the surface within the application zone. The Rubinstein patent discloses a device in which a portion (generally 20) is positioned internally with respect to a user, and another portion is positioned externally with respect to a user (45), as illustrated in Fig. 5 of the Rubinstein patent. The disc protector 45 is designed both to protect a user from escaping substances (see col. 5 lines 1-3 of the Rubinstein patent), and to become moistened with medicant to treat external hemorrhoids (see col. 5, lines 48-51 of the Rubinstein patent). The Rubinstein patent does not disclose a device that is adapted to be positioned entirely within a user. Such a construction of the Rubinstein device would render the Rubinstein device at least partially non-functional. For at least these reasons, Applicant submits that claim 1 is patentable over the Rubinstein patent.

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Claims 2-10, 14, 33-35, 37, and 38 are patentable because they depend from claim 1, which, as stated above, is patentable over the Rubinstein patent.

Claim 39 as amended is directed to an absorbent device adapted to deliver a therapeutic agent to a user. The device includes a body having a proximal end and a distal end and adapted to be positioned entirely within the user. The body includes an absorbency zone adjacent the distal end, wherein the absorbency zone includes absorbent material; an application zone adjacent the proximal end and spaced apart from the distal end; a reservoir within the application zone; and a formulation including a therapeutic agent positioned substantially within the reservoir in the application zone. The Rubinstein patent discloses a device in which a portion (generally 20) is positioned internally with respect to a user, and another portion is positioned externally with respect to a user (45), as illustrated in Fig. 5 of the Rubinstein patent. The disc protector 45 is designed both to protect a user from escaping substances (see col. 5 lines 1-3 of the Rubinstein patent), and to become moistened with medicant to treat external hemorrhoids (see col. 5, lines 48-51 of the Rubinstein patent). The Rubinstein patent does not disclose a device that is adapted to be positioned entirely within a user. Such a construction of the Rubinstein device would render the Rubinstein device at least partially non-functional. For at least these reasons, Applicant submits that claim 39 is patentable over the Rubinstein patent.

Claims 40-42 are patentable because they depend from claim 39, which, as stated above, is patentable over the Rubinstein patent.

Claim 44 as amended is directed to a method for producing a device for delivering a therapeutic agent to a user. The method includes manufacturing a tampon having a body with a distal end, a proximal end, an absorbency zone adjacent the distal end, and an application zone adjacent the proximal end, wherein the body is adapted to be positioned entirely within the user, and wherein the application zone has a surface; and locating a formulation including a therapeutic agent substantially adjacent the surface within the application zone. The Rubinstein patent discloses a device in which a portion (generally 20) is positioned internally with respect to a user, and another portion is positioned externally with respect to a user (45), as illustrated in Fig. 5 of the Rubinstein patent. The disc protector 45 is designed both to protect a user from escaping substances (see col. 5 lines 1-3 of the Rubinstein patent), and to become moistened with medicant to treat external hemorrhoids (see col. 5, lines 48-51 of the Rubinstein patent). The Rubinstein patent does not disclose a device that is adapted to be positioned entirely within a user. Such a construction of the Rubinstein device would render the Rubinstein device at least partially non-functional. For at least these reasons, Applicant submits that claim 44 is patentable over the Rubinstein patent.

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Claims 45, 47, 48, and 50 are patentable because they depend from claim 44, which, as stated above, is patentable over the Rubinstein patent.

Claim 51 as amended is directed to a tampon for delivering a therapeutic agent to a user. The tampon includes a body having a distal end, an absorbent portion adjacent the distal end, and an application zone spaced apart from the distal end, wherein the body is adapted to be positioned entirely within the user, and a means for carrying a therapeutic agent within the application zone. The Rubinstein patent discloses a device in which a portion (generally 20) is positioned internally with respect to a user, and another portion is positioned externally with respect to a user (45), as illustrated in Fig. 5 of the Rubinstein patent. The disc protector 45 is designed both to protect a user from escaping substances (see col. 5 lines 1-3 of the Rubinstein patent), and to become moistened with medicant to treat external hemorrhoids (see col. 5, lines 48-51 of the Rubinstein patent). The Rubinstein patent does not disclose a device that is adapted to be positioned entirely within a user. Such a construction of the Rubinstein device would render the Rubinstein device at least partially non-functional. For at least these reasons, Applicant submits that claim 51 is patentable over the Rubinstein patent.

Claim 53 is patentable because it depends from claim 51, which, as stated above, is patentable over the Rubinstein patent.

7. Rejection of Claim 38 as Obvious

In the Office Action mailed November 22, 2002, the Examiner rejects claim 38 as being unpatentable under 35 U.S.C. §103(a) over the Rubinstein patent. Applicant respectfully traverses the rejection.

First, claim 38 is patentable because it depends from claim 1, which, as stated above, is patentable over the Rubinstein patent.

Alternatively, with respect to the Rubinstein patent, the Examiner believes the Rubinstein patent "discloses the invention substantially as claimed." The Examiner, however, acknowledges that the Rubinstein patent does not disclose that the formulation includes a polymeric material. The Examiner believes it is well known in the art to include polymeric materials in treatment formulations, and that it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the Rubinstein device with a formulation that has a polymeric material.

The Examiner has not established a *prima facie* case of obviousness because he does not provide a reference indicating that polymeric materials are well known in the art in association with treatment formulations. In addition, the Examiner does not identify why one of skill in the art would

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have been motivated to modify the device of the Rubinstein patent with polymeric materials. Therefore, Applicant respectfully submits that claim 38 is patentable over the Rubinstein patent, and that the rejection should be withdrawn.

8. Remarks on Paragraph 12 of the Office Action mailed on November 22, 2002

In paragraph 12 of the Office Action mailed November 22, 2002, the Examiner objects to claims 7, 35, 37, 47, and 48 as being dependent upon a rejected base claim. However, the Examiner indicates that the claims would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The Applicant appreciates the Examiner's acknowledgement of the allowable subject matter of claims 7, 35, 37, 47, and 48. As described above, Applicant has added new claim 55 to include the subject matter of claims 1 and 7. In addition, Applicant has added new claim 56 to include the subject matter of claims 44 and 47. Therefore, Applicant respectfully submits that claims 55 and 56 are patentable over the references cited by the Examiner.

In conclusion, and in view of the remarks set forth above, Applicants respectfully submit that the application and the claims are in condition for allowance and respectfully request favorable consideration and the timely allowance of pending claims 1-14, 17-42, 44-53, and 55-56. If any additional information is required, the Examiner is invited to contact the undersigned at (920) 721-8863.

The Commissioner is hereby authorized to charge any prosecutorial fees (or credit any overpayment) associated with this communication to Kimberly-Clark Worldwide, Inc. deposit account number 11-0875. If a fee is required for an extension of time under 37 C.F.R. 1.136 not accounted for above, such extension is requested and should also be charged to our Deposit Account. A duplicate of this sheet is provided.

Respectfully submitted,

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CERTIFICATE OF FACSIMILE TRANSMISSION

I, Cynthia M. Trudell, hereby certify that on May 22, 2003, this document is being transmitted via facsimile to: Assistant Commissioner for Patents, Right Fax No. 703-872-9302.

By: Cynthia M. Trudell
Cynthia M. Trudell